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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,604	12/17/2001	Chi-Yue Wu	179.7294USU	2907

7590

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EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/22/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,604

Applicant(s)

WU ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's Response dated June 18, 2003

1. In the Response filed June 18, 2003, claims 1-7 were canceled, and claims 8-11 were amended. Applicant presented arguments directed to the rejection of claims 8-13 under 35 U.S.C. 102(b) as being anticipated by *Konoshima Saponis Used in Traditional and Modern Medicine*, 1996, pages 86-101 (Konoshima) and to the rejection of claims 8-13 under 35 U.S.C. 102(e) as being anticipated by Bombardelli et al. US Patent 6,280,777 B1 (Bombardelli). Claims 8-13 are pending. An action on the merits of claims 8-13 is contained herein below.
2. The objection to claims 4-7 and 8-9 as being substantial duplicates of claims 1 and 2-3, respectively, has been rendered moot by applicant's amendment dated June 18, 2003.
3. The rejection of claims 1-2, 4-8, and 10-13 under 35 U.S.C. 112, second paragraph, has been rendered moot by applicant's amendment dated June 18, 2003.
4. The rejection of claims 8-13 under 35 U.S.C. 102(b) as being anticipated by *Konoshima Saponis Used in Traditional and Modern Medicine*, 1996, pages 86-101 (Konoshima) and to the rejection of claims 8-13 under 35 U.S.C. 102(e) as being anticipated by Bombardelli et al. US Patent 6,280,777 B1 (Bombardelli) is maintained for the reasons of record as set forth in the Office Action dated February 14, 2003.

Objections/Rejections Set For the in Office Action dated February 14, 2003

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by *Konoshima Saponis Used in Traditional and Modern Medicine*, **1996**, pages 86-101 (Konoshima).

Konoshima discloses saponin derivatives of formula (I) and methods for treating conditions associated with sialyltransferase as claimed by applicant. Glycosides disclosed by Konoshima corresponding to the instantly claimed saponin derivatives of formula (I) include wistariasaponin C, soyasaponin I, and soyasaponin II (page 88; compounds **4**, **7**, and **8**). Konoshima further discloses soyasaponin I as a valuable anti-tumor-promoter when co-administered with afromosin to mice (pages 90-91).

7. Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Bombardelli et al. US Patent 6,280,777 B1 (Bombardelli).

Bombardelli discloses saponin derivatives of formula (I) and methods for treating conditions associated with sialyltransferase as claimed by applicant. Bombardelli discloses a method for treating cancer by administering to a subject in need of such treatment a therapeutically effective amount of a soya extract (column 4, lines 46-52) comprising a content of glucoside isoflavones of at least 13% by weight and a content of 0.6 to 1.5 parts by weight of group 3 soya saponins per 1 part by weight of glucoside isoflavones (column 4, lines 36-41). Saponins disclosed as having such a beneficial

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effect include soyasaponin I, soyasaponin II, soyasaponin III, soyasaponin IV, soyasaponin V, and soyasaponin II isomer (column 5, lines 21-54).

Response to Arguments

8. Applicant's arguments filed June 18, 2003 have been fully considered but they are not persuasive.

Applicant argues: 1) the mechanism of sialyltransferase is totally different from that of 12-O-tetradecanoylphorbol-13-acetate (TPA) which is used in Konoshima to promote tumors and 2) persons skilled in the art cannot infer the sialyltransferase-inhibiting activity of saponins based on the teachings of Bombardelli as Bombardelli teaches saponins as having anti-proliferative activity, which is not substantively related to the activity of sialyltransferase.

The examiner respectfully disagrees, as it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Claim 10 is drawn to a method of inhibiting sialyltransferase, which comprising contacting the sialyltransferase with a saponin derivative of general formula (I) or the pharmaceutically acceptable salts and esters thereof. Claim 11 is drawn to a method of treating the conditions associated with the sialyltransferase, which comprises administration of the saponin derivative of general formula (I) to a patient suffering from, or susceptible to, such a condition. Claims 8-9 depend from claim 10, and claims 12-13 depend from claim 11.

Glycosides disclosed by Konoshima corresponding to the instantly claimed saponin derivatives of formula (I) include wistariasaponin C, soyasaponin I, and soyasaponin II (page 88; compounds 4, 7, and 8). Konoshima discloses soyasaponin I as a valuable anti-tumor-promoter when co-administered with afromosin to mice (pages 90-91). Saponins disclosed by Bombardelli include soyasaponin I, soyasaponin II, soyasaponin III, soyasaponin IV, soyasaponin V, and soyasaponin II isomer (column 5, lines 21-54). Bombardelli discloses a method for treating cancer by administering to a subject in need of such treatment a therapeutically effective amount of a soya extract (column 4, lines 46-52) comprising a content of glucoside isoflavones of at least 13% by weight and a content of 0.6 to 1.5 parts by weight of group 3 soya saponins per 1 part by weight of glucoside isoflavones (column 4, lines 36-41). Conditions disclosed by applicant as associated with sialyltransferase include inflammation, allergy, infection by pathogens, oncogenesis, cancer, metastasis, and invasion caused by sialyltransferase (page 9, lines 7-12).

Both Konoshima and Bombardelli disclose compounds of formula (I) as claimed by applicant. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the compounds as disclosed by Konoshima and Bombardelli inherently possess sialyltransferase inhibition activity.

Furthermore, both Konoshima and Bombardelli disclose administration of compounds of formula (I) to a patient suffering from a tumor/cancer. A reference anticipates a claim of a patent if the reference contains adequate directions for the practice of the invention claimed. See *Dewey & Almy Chemical Co., et al. v. Mimex Co., Inc.* 124 F.2d 986, 52 USPQ 138 (2d Cir. 1942). In construing the process claims in suit and the references, it is an identity of manipulative operations (i.e. contacting the sialyltransferase with a saponin derivative of general formula (I) or administration of the saponin derivative of general formula (I) to a patient), which leads to a finding of anticipation. It is settled that the scientific explanation for an invention is unimportant in considering patentability. *De Forest Radio Co. v. General Electric Co.*, 283 U.S. 664, 686, 9 USPQ 297, 304 (1931). More specifically, in order to anticipate a claimed process, a reference need not disclose the scientific effects, which are inherent to the process. See *Templeton Patents, Ltd. V. J.R. Simplot Co.*, 336 F.2d 261, 142 USPQ 428 (9th Cir. 1964). See also *Nossen et al. v. United States*, 152 USPQ 619 (US Cl Ct 1967).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has failed to particularly point out the identity of the modifications to the pentose or hexose residue which distinctly set forth the structural core modifications or chemical moieties effectuating said derivatization. In the absence of distinct modifications or derivatizing moieties, the term "derivatives" is indefinite in all occurrences. Compounds of formula (I) are also seen to be incomplete when $m = 0$. When $m = 0$, R_4 is not present resulting in a carbon atom with an incomplete valence. In the absence of an indication of R_4 being 1, 2, or 3, claims reading of compounds of formula (I) are indefinite in all occurrences.

Conclusion

11. Claims 8-13 are pending. Claims 8-13 are rejected. No claims are allowed.
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

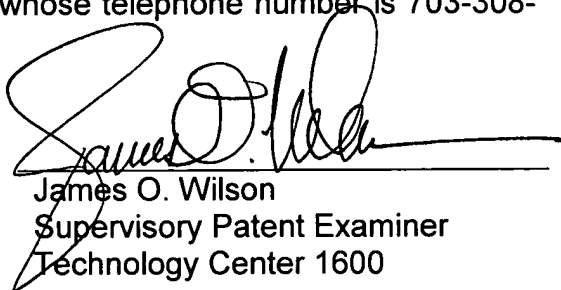
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
August 19, 2003